DEVICE AND METHOD FOR PERFORMING A DIAGNOSTIC TEST

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The application claims the benefit of and priority to U.S. Prov. Pat. App. Ser. No. 61/533,959 filed 13 Sep. 2011 and entitled "DEVICE AND METHOD FOR PERFORMING A DIAGNOSTIC TEST," the entirety of which is incorporated by reference.

BACKGROUND

[0002] Sampling and testing of biological samples and body fluids (e.g., saliva, blood, urine, fecal matter, foods, plants, fish, minerals, animals, etc) is common for both testing and monitoring humans, fish, animals, and plants for any number of biochemical or physiological conditions and, of course, for determining the general state of health of an organism. For example, sampling and testing of human body fluids is often performed for point-of-care testing ("POCT"). POCT is defined as medical testing at or near the site of patient care. The driving notion behind POCT is to bring the test conveniently and immediately to the patient. This increases the likelihood that the patient, physician, and care team will receive the results more quickly, which allows for immediate clinical management decisions to be made. POCT examples include, but are not limited to blood glucose testing, hormone testing, cardiac pulmonary, gastroenterology, urology, dermatology, neurology, pediatrics, surgical, public health, bioterrorism, food safety, and veterinary and plant pathology testing, metabolic testing (e.g., thyroid stimulating hormone), blood gas and electrolytes analysis, rapid coagulation testing, rapid cardiac markers diagnostics, drugs of abuse screening, urine testing, pregnancy testing, fecal occult blood analysis, food pathogen screening, complete blood count ("CBC"), hemoglobin diagnostics, infectious disease testing, cholesterol screening cancer testing (e.g. PSA), hormone testing (hCG, LH, FSH), cardiac (troponin), pulmonary, gastroenterology (e.g., H. pylori antibodies), urology, dermatology, neurology, pediatrics, surgical, and public health (Ebola, cholera, HIV), and combinations thereof.

[0003] One testing method that is often employed for POCT and more conventional testing involves the use of lateral-flow chromatographic immunoassay cassettes. Lateral-flow chromatographic immunoassay cassettes can be used to easily and quickly obtain a variety of qualitative results relating to a number of biochemical and physiological conditions and disease states of an individual. These kinds of tests require the end user to simply add a sample to the cassette and then observe the result a few minutes later. Since such rapid and easy-to-use tests are user friendly, they are very popular in both the professional and consumer markets nowadays. Such tests are also very popular in areas where access to trained health care professionals is limited or where access to proper medical facilities is limited (e.g., poor areas, developing countries, war zones, etc).

[0004] Lateral flow chromatographic immunoassay methods and devices have been described extensively. See, e.g., Gordon and Pugh, U.S. Pat. No. 4,956,302; H. Buck, et al., WO 90/06511; T. Wang, U.S. Pat. No. 6,764,825; W. Brown, et al., U.S. Pat. No. 5,008,080; Kuo and Meritt, U.S. Pat. No. 6,183,972, EP 00987551A3. Such assays involve the detection and determination of an analyte substance that is a member of a specific binding pair consisting of a ligand and a receptor. The ligand and the receptor are related in that the receptor specifically binds to the ligand, being capable of distinguishing a specific ligand or ligands from other sample constituents having similar characteristics. Immunological assays involving reactions between antibodies and antigens are one such example of a specific binding assay. Other examples include DNA and RNA hybridization reactions and binding reactions involving hormones and other biological receptors. One well-known commercial embodiment of this technique is the Clearblue One-Step Pregnancy Test.

[0005] Lateral flow chromatographic immunoassay test cassettes have a number of desirable characteristics including their ease of use and broad applicability to a variety of analytes. Likewise, immunoassay procedures capable of being carried out on a test strip and which can be administered in the field or other locations where medical testing laboratories are not readily available have provided a great benefit to the diagnosis and control of disease. Currently, however, such lateral flow chromatographic immunoassay tests are generally only capable of providing qualitative results. That is, while currently available lateral flow chromatographic immunoassay test cassettes and cassette reader apparatuses are particularly well-suited for telling a practitioner whether or not one or more test substances are present in a sample above a given detection limit, they are poorly suited for providing quantitative results. There is an ongoing need in the art for devices and methods that combine the ease of use characteristics of lateral flow chromatographic immunoassay tests with systems that are designed to provide quantitative results. Such devices and methods may, for example, allow medical practitioners to diagnose a variety of conditions at the point of care (e.g., chair-side or essentially anywhere in the world) without being tied to a medical facility or a testing laboratory.

BRIEF SUMMARY

[0006] A device and method for performing a point of care diagnostic test for detecting and quantifying at least one analyte in a biological sample (e.g., a body fluid). In one embodiment, the device disclosed herein may include an immunoassay apparatus (i.e., a lateral flow immunochromatographic assay cassette) and a sample holder with an adjustable variable angle stage for positioning the immunoassay apparatus relative to a light source and a detector device to optimize elastic light scattering. In another embodiment, the device includes an interface for a light source (e.g., an optical fiber or light pipe), an interface (e.g., a collimating lens) for a external digital imager (e.g CCD or CMOS chip), and an adjustable variable angle stage that positions a lateral flow immunochromatographic assay cassette so as to optimize the angle of incidence and angle of radiation to optimize an elastic light scattering signal from the a lateral flow immunochromatographic assay cassette. The device is based upon elastic light scattering, so the variation in the angle of incidence and angle of reflection are optimized to maximize signal generation due to elastic light scattering.

[0007] In one embodiment, the first angle between the light source (i.e., incident light) and the immunoassay apparatus, and the second angle between the detector device and the immunoassay apparatus (i.e., elastically scattered light) is adjustable to improve at least one of a signal-to-noise ratio or a detection limit for the at least one analyte. Optimizing these two angles enables the user to maximize the elastic light